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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,597	04/30/2001	Antoni P. Tomsia	IB-1627	3236

8076 7590 07/25/2007

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ART UNIT	PAPER NUMBER
1771	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED
JUL 25 2007
GROUP 1700

Application Number: 09/845,597
Filing Date: April 30, 2001
Appellant(s): TOMSIA ET AL.

R'Sue Popowich Caron
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 26, 2007 appealing from the Office action mailed September 27, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Pazo, A. et al. "HA-bioactive glass composites: High temperature reactivity and 'in-vitro' behavior" Scripta Materialia, Volume 34, No. 11 (1996), pp. 1729 - 1733

Gomez-Vega, et al. "Glass-hydroxyapatite coatings on titanium-based implants" Ceramics Transactions (December 1999)

Gomez-Vega, J.M. et al., "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," Biomedical Materials: Drug Delivery Implants and Tissue Engineering, Mater. Res. Soc. Svm . Proc. (1999) pp. 349-354

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 111 (b)(1) as follows:

> Section 35 USC 111 (b)(1) states:
>
> Such application shall include- (A) a specification as prescribed by the first paragraph of section 112 of this title.
>
> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's claim for priority to Provisional Application 60/201,556 is denied. The provisional application contains a collection of articles which are not seen to provide support for the claimed invention. It should be noted that the IDS designates three articles as Prior Art which are also included as part of the "Provisional Application." Specifically, the specification of the provisional application does not meet the requirements of a "specification" according to 37 CFR 1.77 (b) and (c), which necessitates a certain format and subject matter for a specification. The present collection of previously published articles, including ones not even written by the

inventors, does not comply with 37 CFR 1.77 (b) and (c). Therefore, priority to said provisional application is denied.

Claim Rejections - 35 USC § 102

Claims 1, 8 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by the article titled "HA-bioactive glass composites: High temperature reactivity and 'in- vitro' behavior" by Pazo, et al.

Regarding claim 1, the reference teaches a multilayered article (see text of page 1733 and Figures 6 and 7) comprising a Ti or Ti alloy substrate (see line 6 of abstract) and a first layer comprising a glass of the claimed composition (see page 1729, first paragraph under "Materials and Methods), further comprising HA in an amount of 25% (up to 50%) (page 1729, last paragraph).

Regarding claim 8, the substrate is Ti or Ti alloy (abstract line 6).

Regarding claim 23, the reference teaches the amount of SiO2 within the claimed range (page 1729, first paragraph under "Materials and Methods").

Claims 1, 3, 5, 8-12, and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published February 2000.

Regarding claim 1, the reference teaches a multilayer article (see bottom of page 16) comprising a metal substrate (see abstract), and a first layer comprising the claimed glass composition (Table I, samples 6P55, 6P57, 6P61) and an amount of HA within the claimed range (bottom of page 16).

Regarding claim 3, the reference teaches the article of claim 1 having multiple

layers (intermediate layers) (page 19, lines 1-8) comprising a glass composition as defined in claim 1 (see Table I).

Regarding claim 5, the reference teaches the article of claim 3 having a first intermediate layer having a HA concentration of 0%, a second intermediate layer having a HA concentration of 20%, and a first layer having a HA concentration of 40% (page 19, lines 1-8).

Regarding claim 8, the reference teaches the article of claim 1 wherein the substrate is Ti-6Al-4V (see abstract).

Regarding claims 9-12, the reference teaches the claimed glass compositions on a substrate of Ti-6Al-4V and HA concentrations meeting the claim limitations (Table I and bottom of page 16).

Regarding claim 20, the reference discloses a multilayer article comprising a Ti6Al4V substrate (see abstract) having a first layer and 2 intermediate layers, the layers comprising the claimed glass composition (see Table I) and an amount of HA within the claimed range (bottom of page 16).

Regarding claims 21 and 23, Table I shows the SiO_2 content of samples 6P55 and 6P57 to be within the claimed range.

Regarding claims 22 and 24, the bottom of page 16 teaches n=2.

Regarding claims 25 and 27, Table I shows the SiO2 content of sample 6P61 to be within the claimed range.

Regarding claims 26 and 28, the bottom of page 16 teaches n=2.

Claim Rejections - 35 USC § 103

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published February 2000 as applied above, and further in view of "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," by Gomez-Vega et al, published 1999.

While the 2000 Gomez-Vega reference discloses a multilayer article as presently claimed wherein n=2 (having a second intermediate layer between the first intermediate layer and the substrate), the reference is silent with respect to a SiO2 gradient wherein the highest SiO2 concentration is closest to the substrate. The reference further states that a desired quality in the multilayer article is good adhesion of the coatings to metal (Introduction, the paragraph that spans the bottom of page 15 to the top of page 16). The 1999 Gomez-Vega reference teaches a multilayer article having a metal substrate, glass layers having the claimed composition, and an outer layer having HA particles embedded therein, further having an SiO2 gradient wherein the highest SiO2 concentration is closest to the substrate to achieve excellent adhesion to the metal substrate. Therefore, since excellent adhesion to the substrate is a desirable quality in the multilayer article of the 2000 Gomez-Vega reference, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the multilayer article having an HA gradient according to the 2000 Gomez-Vega reference with the 1999 Gomez-Vega reference to achieve excellent adhesion to the metal substrate.

(10) Response to Argument

In response to Appellant's argument that "HA-bioactive glass composites: High temperature reactivity and 'in- vitro' behavior" Pazo, et al. do not teach a multi-layered structure with a metal substrate and a first layer with the specified glass composition. Appellant argues that none of the samples in the reference used a metal substrate in conjunction with a glass layer. It should be noted that "disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Furthermore, in the "Introduction" section of the article, Pazo et al. indicate that the glass composition demonstrates excellent adhesion to Ti and Ti alloys. The Examiner submits that the article discusses multiple materials being adhered together and thus Appellant's "multi-layered" structure.

In response to Appellant's argument that the rejection as anticipated by "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez- Vega et al. published February 2000 cannot be considered prior art under 102(b), the Examiner respectfully argues the contrary. As noted above, Appellant has not been granted priority to U.S. Provisional Application 60/201,556, filed May 1, 2000 because the U.S. Provisional Application fails to meet the requirements of a Provisional Application. The Provisional Application contains a collection of six separate articles, some published more than one year prior to the U.S. filing date, which are not seen to provide support for the claimed invention. Applicant has pointed to several passages in an effort to show support for isolated elements of the present claims. Those passages are from different unconnected documents. In particular, claim 1 requires that the "glass composition

contains hydroxyapatite particles in an amount of *up to* 50 wt%." Appellant points to passages describing 50% by weight of hydroxyapatite particles but no passage supporting the range "up to". It should be noted that the IDS designates three articles as Prior Art which are also included as part of the "Provisional Application." Specifically, the specification of the provisional application does not meet the requirements of a "specification" according to 37 CFR 1.77 (b) and (c), which necessitates a certain format and subject matter for a specification. The present collection of previously published articles, including ones not even written by the inventors, does not comply with 37 CFR 1.77 (b) and (c). In regards to inventorship, articles in the Provisional Application include an additional author, A. Pazo, which is not listed as an inventor in the instant application. In light of the above listed deficiencies, priority to the provisional application is denied. As a result, the Appellant has only been granted priority to the April 30, 2001 filing date of the present application. The article used in the rejection was published in February 2000 and can be considered as prior art under 102(b).

In response to Appellant's arguments regarding the 35 USC 103 rejection of claim 30, in view of the above remarks, that rejection is also seen to be valid and is herein maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
Jennifer Chriss

Conferees:

Terrel Morris

Carol Chaney